K023653

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

JAN 17 2003

1. Name of Submitter, Contact Person and Date Summary Prepared:

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21250 Hawthorne Blvd., Suite 560
Torrance, California 90503
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Summary Prepared On: October 29, 2002

2. Device Name:

Trade/Proprietary Name:	MaxOne™ IV Fluid/Blood Warmer, Model 102
Common/Usual Name:	Blood, Blood Products and IV Fluid Warmer
Classification Name:	Infusion Fluid Thermal Warmer and Non-electromagnetic Radiation Blood Warmer and Blood and Plasma Warming Device

3. Legally Marketed Equivalent Device Name:

We are claiming substantial equivalence to the MaxOne™ IV Fluid/Blood Warmer, Model 101, cleared 510(k) K002409.

4. Description of the Device:

The MaxOne™ IV Fluid/Blood Warmer consists of a single reusable heating unit with controller containing an on/off switch to be used with disposable MaxOne™ Warmer Cartridges. The device is placed in-line between a standard IV drip set and a standard IV extenstion set and is designed to warm blood, blood products and intravenous liquids at flow rates of up to and including 150 mL/min. The MaxOne™ IV Fluid/Blood Warmer will deliver temperatures at 37°C to 41.5°C.

The MaxOne™ IV Fluid/Blood Warmer opens up to reveal the aluminum heating plates. A disposable sterile MaxOne™ Warmer Cartridge is placed on the supporting pins of the aluminum heating plates. Blood, blood products and intravenous solutions travel through channels in the warmer cartridge, which is surrounded by heating channels and heated by means of electrical resistance. The device meets the requirements of UL-2601 and CAN/CSA C22.2360.1.1 M90.

5. *Intended Use of the Device*

The MaxOne™ IV Fluid/Blood Warmer is indicated for the warming of blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments.

6. *Comparison of technological characteristics With Predicate Device*

The MaxOne™ IV Fluid/Blood Warmer, Model 102, is substantially equivalent to the MaxOne™ IV Fluid/Blood Warmer, Model 101, cleared 510(k) K002409.

Comparison of Technological Features

Features	MaxOne™ Model 101	MaxOne™ Model 102
Heating method	Aluminum heating plates formed to accept warming cartridge, electrical resistance	Aluminum plates formed to accept warming cartridge, electrical resistance
Fluid contact product to be used with heating unit	MaxOne™ Warmer Cartridge, a sterile polycarbonate disposable cartridge	MaxOne™ Warmer Cartridge, a sterile polycarbonate disposable cartridge
Temperature controls	3 thermistors	4 thermistors
Alarm	Audio/visual	Audio/visual
Alarm conditions	When temperature reaches 40°C	When temperature reaches 44°C
Electronics	Microprocessor control	Microprocessor control
Operation	110v AC	110v AC
Flow	5 - 150 mL/min	1 - 150 mL/min
Infusion Temp	33°C - 39°C	37°C – 41.5°C
Dimensions	3.25"W x 1.7"L x 9.7"H	3.25"W x 1.7"L x 9.7"H
Weight	2 lbs. 10 oz.	2 lbs. 10 oz.

7. *Discussion of Non-clinical Studies*

Results of studies conducted on the sterile disposable MaxOne™ Warmer Cartridge demonstrate the material to be biocompatible for its intended use. In addition, performance data demonstrate the temperature accuracy of the device at different flow rates.

8. Conclusion

The MaxOne™ IV Fluid/Blood Warmer, Model 102, has the same technological characteristics and intended use as the Model 101. Therefore, the Model 102 does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 17 2003

Automatic Medical Technologies, Incorporated
C/O Ms. Cindy Martin
The Regulatory Consultants
1711 North Bush Street
Santa Ana, California 92706

Re: K023653
Trade/Device Name: MaxOne™ IV Fluid/Blood Warmer, Model 102
Regulation Number: 864.9205
Regulation Name: Blood and Plasma Warming Device
Regulatory Class: II
Product Code: LGZ
Dated: October 29, 2002
Received: October 30, 2002

Dear Ms. Martin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications For Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: MaxOne™ IV Fluid/Blood Warmer, Model 102

Indications For Use:

The MaxOne™ IV Fluid/Blood Warmer, Model 102, is indicated for the warming of blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (✓) OR Over-The-Counter Use ( )

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023653